

We Claim:

1 1. A disposable glucose test strip for use in a
2 test meter of the type which receives a disposable test
3 strip and a sample of blood from a patient and performs an
4 electrochemical analysis of the amount of glucose in the
5 sample, comprising:

6 (a) a substrate;
7 (b) a reference electrode;
8 (c) a working electrode, said working electrode
9 comprising a conductive base layer disposed on the substrate
10 and a first working coating disposed over the conductive
11 base layer, said first working coating comprising a filler
12 having both hydrophobic and hydrophilic surface regions such
13 that it forms a network upon drying, an enzyme effective to
14 oxidize glucose, and a mediator effective to transfer
15 electrons from the enzyme to the conductive base layer; and
16 (d) means for making an electrical connection
17 between the reference and working electrode and a glucose
18 test meter.

1 2. The test strip of claim 1, wherein the
2 working layer is non-conductive.

1 3. The test strip of claim 2, wherein the filler
2 is silica.

SELF.P-005-US
PATENT APPLICATION

1 4. The test strip of claim 3, wherein the
2 conductive base layer comprises conductive carbon.

1 5. The test strip of claim 3, wherein the enzyme
2 is glucose oxidase.

1 6. The test strip according to claim 3, wherein
2 the mediator is ferricyanide.

1 7. The test strip of claim 3, wherein the first
2 working layer is formed from an aqueous composition
3 comprising weight 2 to 10 % by weight of a binder 3 to 10 %
4 by weight of silica; 8 to 20 % by weight of a mediator; and
5 1000 to 5000 units per gram of the aqueous composition of an
6 enzyme for oxidizing glucose.

1 8. The test strip of claim 3, wherein the silica
2 is Cab-o-Sil TS610.

1 9. The test strip of claim 8, wherein the
2 conductive base layer comprises conductive carbon.

1 10. The test strip of claim 8, wherein the enzyme
2 is glucose oxidase.

1 11. The test strip of claim 8, wherein the
2 mediator is ferricyanide.

1 12. The test strip of claim 8, wherein the first
2 working layer is formed from an aqueous composition
3 comprising weight 2 to 10 % by weight of a binder 3 to 10 %
4 by weight of silica; 8 to 20 % by weight of a mediator; and
5 1000 to 5000 units per gram of the aqueous composition of an
6 enzyme for oxidizing glucose.

1 13. The test strip of claim 3, further comprising
2 a second working layer comprising silica, a binder and a
3 mediator but no glucose-oxidizing enzyme.

1 14. The test strip of claim 3, further comprising
2 a second working layer comprising silica and a binder but no
3 glucose-oxidizing enzyme.

1 15. The test strip of claim 1, further comprising
2 a second working layer comprising a filler, a binder and a
3 mediator but no glucose-oxidizing enzyme.

1 16. The test strip of claim 1, further comprising
2 a second working layer comprising a filler and a binder but
3 no glucose-oxidizing enzyme.

1 17. An aqueous composition comprising a binder, a
2 ~~silica~~¹ filler having both hydrophobic and hydrophilic surface
3 regions, at least one of an enzyme effective to oxidize
4 glucose and an electron transfer mediator.

1 18. The composition of claim 17, wherein the
2 filler is non-conductive.

1 19. ~~The composition of claim 18, wherein the~~
2 filler is ~~silica~~²

1 ¹⁹
2 20. An aqueous composition comprising 2 to 10 %
3 by weight of a binder; 3 to 10 % by weight of silica; 8 to
4 20 % by weight of a mediator; and 1000 to 5000 units per
5 gram of the aqueous composition of an enzyme for oxidizing
glucose.

1 ²⁰
2 ¹⁹
21. The composition of claim ²⁰²¹, wherein the
silica ^{has}
^ both hydrophobic and hydrophilic surface regions.

1 ²¹
2 ²⁰
22. The composition of claim ²¹²², wherein the
binder is hydroxyethylcellulose.

SELF.P-005-US
PATENT APPLICATION

24
1 25. A method for making a disposable test strip
2 for the electrochemical detection of glucose, comprising the
3 steps of:

4 (a) applying working and reference electrode
5 tracks to a substrate;

6 (b) applying a conductive base layer in contact
7 with the working electrode track; and

8 (c) applying a working layer over the conductive
9 base layer, wherein the working layer comprising a filler
10 having both hydrophobic and hydrophilic surface regions such
11 that it forms a network upon drying, an enzyme effective to
12 oxidize glucose, and a mediator effective to transfer
13 electrons from the enzyme to the conductive base layer.

24

31
32. The method of claim 31, wherein the silica is
2 B1 Cab-o-Sil TS610.

33. A disposable glucose test strip which produces a current indicative of the amount of glucose in a sample applied to the strip in response to an applied voltage, wherein the amount of current generated in response

25

SELF.P-005-US
PATENT APPLICATION

5 to a given amount of glucose varies by less than 10 percent
6 over a temperature range from 20°C to 37°C.

Sub 92

1 34. A disposable glucose test strip which
2 produces a current indicative of the amount of glucose in a
3 sample applied to the strip in response to an applied
4 voltage, wherein the amount of current generated in response
5 to a given amount of glucose varies by less than 10 percent
6 over a hematocrit range of 0 to 60 %.

1 35. A disposable glucose test strip which
2 produces a current indicative of the amount of glucose in a
3 sample applied to the strip in response to an applied
4 voltage, wherein the amount of current generated in response
5 to a given amount of glucose decays by less than 50% in the
6 5 seconds following peak current generation.